

DOCKET NO.: 133087.01901 (100848-1P US)

PATENT

REMARKS

Claims 1-30 were pending in the present application. Claims 25 and 26 have been canceled herein without prejudice to their presentation in another application. Claims 1-11, 18, 24, 29, and 30 have been amended herein, support for which can be found throughout the specification. No new matter has been added. Upon entry of the present Amendment, claims 1-24 and 27-30 will be pending.

As a preliminary matter, Applicants thank the Examiner for indicating that claim 24 is allowed.

I. The Claimed Invention Is Not Indefinite

Claims 1-23, 25, 26, 28, and 30 have been rejected under 35 U.S.C. §112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully request reconsideration.

i) Definition of Variable X

The Action alleges that the definition of variable X is indefinite because of a dangling valency. One skilled in the art would understand that recitation of hydrogen atoms in chemical structures is routinely omitted, and thus the claims as recited are quite clear. However, to be even more clear, Applicants have amended the definition of X from "C" to "CH₂" in the relevant claims, thereby making the valency of the carbon atom even more clear. No change in claim scope is intended. Accordingly, Applicants respectfully request this ground for rejection be withdrawn.

ii) Definition of R² and R³ as "Heteroaryl"

The Action also alleges that the term "heteroaryl" is indefinite because it is not known how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present. Applicants respectfully disagree with the allegation and direct the Examiner's attention to page 22, lines 30-32 and page 23, lines 27-30 of the specification, where the terms "aryl" (e.g., aromatic radicals including both monocyclic aromatic radicals comprising 6 carbon atoms and polycyclic aromatic radicals comprising up to about 14 carbon atoms) and "heterocycle" (e.g., a ring-containing monovalent and divalent

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radicals having one or more heteroatoms, independently selected from N, O and S, as part of the ring structure and comprising at least 3 and up to about 20 atoms in the rings) appear. One skilled in the art would understand that a "heteroaryl" is a type of "heterocycle." Armed with this disclosure, one of skill in the art would recognize what is meant by "heteroaryl." No change in claim scope is intended. Accordingly, Applicants respectfully assert that the term "heteroaryl" is not indefinite and request that this ground for rejection be withdrawn.

iii) Definitions of R⁷ and R⁸

The Action alleges that in the definitions of R⁷ and R⁸, the groups "C₁₋₄alkylamine, indole and imidazole" do not have a point of attachment to the rest of the molecule. Although one skilled in the art would understand that each of the three recited groups does indeed have points of attachment to the rest of the molecule, and would quite well understand where the points of attachment were, solely to render the claims even more clear, Applicants have amended the groups C₁₋₄alkylamine, indole and imidazole, to "C₁₋₄alkylamino, indolyl and imidazolyl" respectively. No change in claim scope is intended. Accordingly, Applicants respectfully request this ground for rejection be withdrawn.

iv) Claim 25

Claim 25 has been rejected because it allegedly fails to narrow any of the claims 1-24, and the intended use recited is allegedly not patentable. Applicants have canceled claim 25 herein, rendering rejection of this claim moot.

II. Claim 26

Claim 26 has been rejected under 35 U.S.C. §101, because it allegedly failed to set forth any steps involved in the method/process. Claim 26 has been canceled herein, rendering rejection of this claim moot.

III. The Claimed Invention is Enabled

Claims 27-29 have been rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to provide an enabling disclosure. Applicants traverse the rejection and respectfully request reconsideration thereof because one skilled in the art would be able to make and use the

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claimed invention without being required to perform undue experimentation.

β -amyloid ($A\beta$) peptide, the major constituent of amyloid plaques, plays a role in the neuropathology of Alzheimer's Disease (AD) and Down's Syndrome. $A\beta$ is generated from the amyloid precursor protein (APP) by two proteases, β -secretase and γ -secretase. One of skill in the art, armed with this information would recognize the nexus between inhibition of γ -secretase activity and $A\beta$ production, and treatment of the recited disorders and/or diseases. Thus, one of skill in the art, armed with the disclosure of the present application, would recognize that the inhibition of γ -secretase activity, observed with compounds of the present invention, would be expected to be useful in treating the disorders and/or diseases recited in the claims. Further, the present application provides methods of preparation of the claimed compounds and describes assays for evaluating the γ -secretase inhibitory activity of the same. Thus, one of skill in the art would be able to prepare compounds of the present invention and evaluate their activity without undue experimentation.

The Action further alleges that the present application does not provide the skilled practitioner with a dose, dosing regimen, or route of administration. Applicants respectfully direct the Examiner's attention to page 26, lines 6-20 of the specification, wherein doses, dosing regimens, and routes of administration are provided. The Examiner has not provided any evidence to support the position that these doses, dosing regimens, and routes of administration would require undue experimentation.

It is also alleged that the skilled practitioner would not know what diseases or symptoms Applicants intend to treat. Applicants respectfully disagree and assert that one of skill in the art is aware of the diseases and symptoms of those diseases linked to abnormal $A\beta$ production, such as, for example, AD and Down's Syndrome. *See* Specification at page 1, lines 16-21.

In light of the foregoing discussion, Applicants assert that one skilled in the art would be able to make and use the claimed invention without being required to perform undue experimentation. Accordingly, Applicants respectfully assert that claims 27-29 are enabled, and request that the claim rejections be withdrawn.

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IV. Conclusion

Upon entry of the present amendments, Applicants respectfully assert that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to contact Applicants' undersigned representative at (610) 640-7859 if there are any questions regarding Applicants' claimed invention.

Respectfully submitted,



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